



Inventor(s): BERGMANN, Andreas et al.
 Appln. No.: 09/381,032 or Patent No.: _____
 Filed: September 15, 1999 or Issued: _____
 M# / Client Ref.
 Title: RECEPTOR BINDING ASSAYS FOR THE DETECTION OF TSH RECEPTOR AUTOANTIBODIES AND REAGENTS AND REAGENT KIT FOR CARRYING OUT SUCH A RECEPTOR BINDING ASSAY

**SMALL ENTITY STATEMENT CLAIMING SMALL ENTITY STATUS
(37 CFR 1.9(d) and 1.27 (c)) - SMALL BUSINESS CONCERN**

I hereby state that I am

- the owner of the small business concern identified below:
 an official of the small business concern empowered to act on behalf of the concern identified below:

NAME OF CONCERN B.R.A.H.M.S Diagnostica GmhH

ADDRESS OF CONCERN Komturstrasse 19-20, D-12099 Berlin, Germany

I hereby state that the above identified small business concern qualifies as a small business concern as defined in 13 CFR 121.12, and referenced in 37 CFR 1.9(d), for purposes of paying reduced fees under Section 41(a) and (b) of Title 35, United States Code, in that the number of employees of the concern including those of its affiliates, does not exceed 500 persons. For purposes of this statement, (1) the number of employees of the business concern is the average over the previous fiscal year of the concern of the persons employed on a full-time, part-time or temporary basis during each of the pay periods of the fiscal year, and (2) concerns are affiliates of each other when either, directly or indirectly, one concern controls or has the power to control the other, or a third party or parties controls or has the power to control both.

I hereby state that rights under contract or law have been conveyed to and remain with the small business concern identified above with regard to the above entitled invention, invented by the above inventor(s) and described in:

- x → the specification filed herewith,
 one → Application No. 09/381,032, filed
 box → Patent No. _____, issued

If the rights held by the above identified small business concern are not exclusive, each small entity individual, concern or organization having rights to the invention is listed in (A) and (B) below and no rights to the invention are held by any person, other than the inventor, who could not qualify under 37 CFR 1.9(d) as an independent inventor if that person had made the invention, or by any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9(g).

(A) FULL NAME of assignee/licensee/grantee/conveyee*

ADDRESS INDIVIDUAL SMALL BUSINESS CONCERN NONPROFIT ORGANIZATION

(B) FULL NAME of assignee/licensee/grantee/conveyee*

ADDRESS INDIVIDUAL SMALL BUSINESS CONCERN NONPROFIT ORGANIZATION

*NOTE: Separate statement is required from each person, concern or organization named in (A) and (B) above having rights to the invention, swearing to his/her/its status as a small entity. (37 CFR 1.27)

I acknowledge the duty to file, in this case, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the entire fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.26(b))

NAME OF PERSON SIGNING

TITLE OF PERSON OTHER THAN OWNER

ADDRESS OF PERSON SIGNING

SIGNATURE

Dr. Andreas Bergmann
Vice President
B.R.A.H.M.S Diagnostica, Gr. 54, 16761 Hennigsdorf

DATE 26.10.1999

FOR UTILITY/DESIGN
CIP/PCT NATIONAL/PLANT
ORIGINAL/SUBSTITUTE/SUPPLEMENTAL
DECLARATIONS

RULE 62 (37 C.F.R.)
DECLARATION AND POWER OF ATTORNEY
FOR PATENT APPLICATION
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

PM & S
FORM

As a below-named inventor, I hereby declare that my residence, post office address and citizenship are as stated below next to my name, and I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the INVENTION ENTITLED RECEPTOR BINDING ASSAYS FOR THE DETECTION OF TSH RECEPTOR AUTOANTIBODIES AND REAGENTS AND REAGENT KIT FOR CARRYING OUT SUCH A RECEPTOR BINDING ASSAY

the specification of which (CHECK applicable BOX(ES))

A. is attached hereto.
 B. was filed on September 15, 1999 as U.S. Application No. 09/381,032
 C. was filed as PCT International Application No. PCT/ EP99/00159 on January 13, 1999

and (if applicable to U.S. or PCT application) was amended on
I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above. I acknowledge the duty to disclose all information known to me to be material to patentability as defined in 37 C.F.R. 1.56. I hereby claim foreign priority benefits under 35 U.S.C. 119(a)-(d) or 365(e) of any foreign application(s) for patent or inventor's certificate, or 365(a) of any PCT International Application which designated at least one other country than the United States, listed below and have also identified below any foreign application for patent or inventor's certificate, or PCT International Application, filed by me or my assignee disclosing the subject matter claimed in this application and having a filing date (1) before that of the application on which priority is claimed, or (2) if no priority claimed, before the filing date of this application.

| PRIOR FOREIGN APPLICATION(S) | Date first Filed open or Published | Date Patented or Granted | Priority Claimed Yes No |
|---|---|-----------------------------|----------------------------|
| Number <u>19801319.1</u> Country <u>Germany</u> | <u>Day/MONTH/Year Filed</u> <u>15 JAN 1998</u> | | X |

I hereby claim domestic priority benefit under 35 U.S.C. 119(e) or 120 and 365(e) of the indicated United States applications listed below and PCT international applications listed above or below and, if this is a continuation-in-part (CIP) application, insofar as the subject matter claimed and disclosed in this application is not otherwise disclosed in such prior applications. I acknowledge the duty to disclose all information known to me to be material to patentability as defined in 37 C.F.R. 1.56 which became available between the filing date of each such prior application and the national or PCT international filing date of this application.

| PRIOR U.S. PROVISIONAL, NONPROVISIONAL AND/OR PCT APPLICATION(S) | Status | Priority Claimed Yes No |
|--|---|----------------------------|
| Application No. (series code/serial no.) <u>PCT/EP99/00159</u> Day/MONTH/Year Filed <u>13 JAN 1999</u> | <u>Pending, abandoned, patented</u> <u>PENDING</u> | X |

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; And further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

And I hereby appoint Pillsbury Madison & Sutro LLP, Intellectual Property Group, 1100 New York Avenue, N.W., Ninth Floor, East Tower, Washington, D.C. 20005-3910, and I hereby appoint Michael J. Diamond, W. Patrick Bergstrom, Jack S. Barukha, Adam H. Hess, Richard H. Zalden, Roger R. Wise, Jay M. Finkelstein, Anita M. Kirkpatrick, Ruth N. Morduch, Stephan C. Glazier, Paul F. McQuade, Glenn J. Perry, Andrew H. Colton, Paul E. White, Jr., Dale S. Lazer, and Mark G. Paulson, to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith and with the resulting patent, and I hereby authorize them to delete names/numbers below of persons no longer with their firm and to act and rely on instructions from me and communicate directly with the person/attorney/firm/organization who will represent this case to them and by whom which I hereby declare that I have consented after full disclosure to be represented unless and if names the above Firm and/or a below attorney in writing to the contrary.

| | | | | | | | |
|-------------------|-------|--------------------|-------|----------------------|-------|----------------------|-------|
| Paul N. Kokolis | 15773 | Dale S. Lazer | 28872 | Mark G. Paulson | 30783 | Michael J. Diamond | 36787 |
| Raymond F. Uppitt | 17519 | Paul E. White, Jr. | 32011 | Stephan C. Glazier | 31361 | W. Patrick Bergstrom | 32456 |
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| Carl G. Imaia | 18781 | Kendrew H. Colton | 30368 | Ruth N. Morduch | 31044 | Adam H. Hess | 41886 |
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| Peter W. Gowday | 25872 | David A. Jakopin | 32995 | Anita M. Kirkpatrick | 32617 | | |

(1) INVENTOR'S SIGNATURE:

| | | | |
|---|---|-----------------------|-------------|
| <u>Signature</u> | | Date: <u>25.10.99</u> | |
| Address | First | Middle Initial | Family Name |
| Residence | Berlin | Germany | Germany |
| Post Office Address (Include Zip Code) | City: <u>Baumjohannerstrasse 47, D-12351 Berlin, Germany</u> State/Foreign Country: <u></u> Country of Citizenship: <u></u> | | |

(2) INVENTOR'S SIGNATURE:

| | | | |
|---|---|-----------------------|-------------|
| <u>Signature</u> | | Date: <u>25.10.99</u> | |
| Address | First | Middle Initial | Family Name |
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| Post Office Address (Include Zip Code) | City: <u>Holsteinische Strasse 28, D-12161 Berlin, Germany</u> State/Foreign Country: <u></u> Country of Citizenship: <u></u> | | |

(FOR ADDITIONAL INVENTORS, check box to attach PAT 116-2 same information for each re signature, name, date, citizenship, residence and address.)

DECLARATION AND POWER OF ATTORNEY

(continued)

ADDITIONAL INVENTORS:

(3) INVENTOR'S SIGNATURE:

| | | |
|--|------------------------|-----------------------|
| <i>[Signature]</i> | | Date: 26/10/99 |
| First Name | Middle Initial | Family Name |
| Residence | City | State/Foreign Country |
| Post Office Address (Include Zip Code) | Country of Citizenship | |
| Wanckebachstrasse 4, D-12099 Berlin, Germany | | |

(4) INVENTOR'S SIGNATURE:

| | | |
|---|------------------------|-----------------------|
| <i>[Signature]</i> | | Date: 26.10.99 |
| First Name | Middle Initial | Family Name |
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| Post Office Address (Include Zip Code) | Country of Citizenship | |
| Lorenzweg 2, D-12099 Berlin, Germany | | |

(5) INVENTOR'S SIGNATURE:

| | | |
|--|------------------------|-----------------------|
| <i>[Signature]</i> | | Date: 26/10/99 |
| First Name | Middle Initial | Family Name |
| Residence | City | State/Foreign Country |
| Post Office Address (Include Zip Code) | Country of Citizenship | |
| Schlossstrasse 50, D-12165 Berlin, Germany | | |

(6) INVENTOR'S SIGNATURE:

| | | |
|---|------------------------|-----------------------|
| | | Date: |
| First Name | Middle Initial | Family Name |
| Residence | City | State/Foreign Country |
| Post Office Address (Include Zip Code) | Country of Citizenship | |

(7) INVENTOR'S SIGNATURE:

| | | |
|---|------------------------|-----------------------|
| | | Date: |
| First Name | Middle Initial | Family Name |
| Residence | City | State/Foreign Country |
| Post Office Address (Include Zip Code) | Country of Citizenship | |

(8) INVENTOR'S SIGNATURE:

| | | |
|---|------------------------|-----------------------|
| | | Date: |
| First Name | Middle Initial | Family Name |
| Residence | City | State/Foreign Country |
| Post Office Address (Include Zip Code) | Country of Citizenship | |

(9) INVENTOR'S SIGNATURE:

| | | |
|---|------------------------|-----------------------|
| | | Date: |
| First Name | Middle Initial | Family Name |
| Residence | City | State/Foreign Country |
| Post Office Address (Include Zip Code) | Country of Citizenship | |